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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,214	03/20/2001	Kenneth Tucker	7969-089-999	1989

7590

08/23/2002

PENNIE & EDMONDS LLP  
1155 Avenue of the Americas  
New York, NY 10036-2711

EXAMINER

SHAHNAN SHAH, KHATOL S

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 08/23/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/813,214

Applicant(s)

TUCKER ET AL.

Examiner

Khatol S Shannan-Shah

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22, 27-29 and 33-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-22, 27-29 and 33-41 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

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## DETAILED ACTION

### *Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12, 17-18, 33-34 and 36 are, drawn to polypeptides, classified in class 530, subclass 350.
- II. Claims 13-16 and 35 are, drawn to antibodies, classified in class 424, subclass 130.1.
- III. Claims 19, 20, 37, 38 are, drawn to vaccines, classified in class 424, subclass 251.1.
- IV. Claims 21, 22 and 39 are, drawn to compositions, classified in class 424, subclass 185.1.
- V. Claims 27-28 and 40-41 are, drawn to a method of producing immune response, classified in class 424, subclass 9.2.
- VI. Claim 29 is, drawn to a method of producing a cultivar of a bacterial species, classified in class 435, subclass 253.1.

2. The inventions are distinct, each from the other because of the following reasons:

Groups I-IV are drawn to structurally and functionally different products. The inventions are shown to be distinct because they are drawn to distinct products, made by different methods and they are physically and functionally distinct molecules.

Groups V and VI are drawn to different methods. The inventions are shown to be distinct because they are drawn to distinct methods, which differ in the method objectives, method steps, reagents and material used.

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Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of group I can be used for protein assays and diagnostic tests such as ELISA.

Inventions III and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the subcombination (i.e antigenic composition) has separate utility such as diagnostic assays.

3. The several inventions above are independent and distinct, each from the other for the reasons stated. They have acquired a separate status in the art as a separate subject for inventive effect and requires independent searches. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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*Election*

5. This application contains claims directed to the following patentably distinct species of the claimed invention:

If applicants choose Group I, (claims 1-12, 17-18, 33-34 and 36) then there are additional election of species:

1a. Please choose one of polypeptide species from claims 1, 2, 5 or 9.

1b. Please choose one of polypeptide sequences from claims 10, 11 or 33 (i. e. SEQ ID NO 1, 2 or 10).

If applicants choose Group II, (claims 13- 16 and 35) then there are additional election of species:

2a. Please choose one of antibody species from claims 13, 14, 15 or 35.

If applicants choose Group III, (claims 19- 20, 37 and 38) then there are additional election of species:

3a. Please choose one of vaccine species from claims 19, 20, 37 or 38.

If applicants choose Group IV, (claims 21- 22 and 39) then there are additional election of species:

4a. Please choose one of composition species from claims 21- 22 and 39.

If applicants choose Group V, (claims 27- 28 and 40-41) then there are additional election of species:

5a. Please choose one of methods from claims 27- 28, 40 and 41.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 9, 29 and 33 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

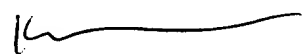
#### ***Conclusion***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on 7:30am-4 pm.

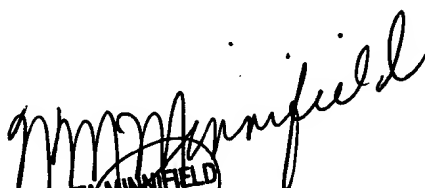
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

 8/15/02  
Khatol Shahnan-Shah, B.S., Pharm., M.S.  
Biotechnology Patent Examiner  
Art Unit 1645

August 10, 2002

  
NITA MINNIFIELD  
PRIMARY EXAMINER  
8/16/02